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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/816,641
Filing Date: March 22, 2001
Appellant(s): JACOBS ET AL.

MAILED
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Group 3700

Mr. Alan A. Limbach
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 22, 2005 appealing from the Office action mailed January 26, 2005 and an Advisory Action mailed May 3, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct with respect to the issue of whether claims 1-2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58 are anticipated or rendered unpatentable over U.S. Patent No. 5,352,229 (Goble), U.S. Patent No. 4,548,202 (Duncan), U.S. Patent No. 5,779,706 (Tschakaloff), and/or U.S. Patent No. (Talpade).

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 1-2, 8, 11-13, 16, 21, 24-26, 46-50 and 54-58 under 35 U.S.C. 112, first paragraph, has been withdrawn. Thus, this issue is moot.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,353,229	GOBLE	10-1994
4,548,202	DUNCAN	10-1985
5,779,706	TSCHAKALOFF	07-1998
6,110,100	TALPADE	08-2000

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 13, 16, 18, 21, 24-26 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble (US 5,352,229).

Regarding **claim 1**, Goble et al. discloses an implantable tissue approximation device since bone can be broadly and reasonably be interpreted to be a form of hard tissue. Nonetheless, functional language is not given patentable weight in apparatus claims and the device of Goble et al. is fully capable of performing the function. The device has a supportive backing **31** having a front side, a back side, and at least one through-hole **33, 34** formed therethrough; and at least one attachment point **35** extending from front side of the backing **31** (column 5, lines 55-68), as shown in Figure 2.

Regarding **claim 2**, wherein said backing **31** that has a shape in the form of an H, as seen in Figure 2.

Regarding **claim 13**, wherein said backing **31** comprises a solid material.

Regarding **claim 16**, wherein said at least one attachment point that includes a shape and direction selected from the group consisting of canted tines, erect tines, canted hooks, canted arrowheads, erect barbed tipped tines, canted barbed tipped tines, erect arrowhead tipped tines, canted arrowhead tipped tines, erect nail-shaped tines, canted nail-shaped tines, and cheese grater-like tines, as shown in Figure 2.

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Regarding **claim 21**, wherein the at least one attachment point that includes a plurality of attachment points and wherein the at least one through-hole is disposed between the attachment points, as shown in Figure 2.

Regarding **claim 24**, wherein the supportive backing is rigid.

Regarding **claim 25**, wherein the supportive backing has a strength sufficient to set fragmented bones (columns 5-6), as shown in Figure 2.

Regarding **claim 26**, wherein the supportive backing defines at least one through hole and includes a plurality of through-holes formed through the supportive backing, as shown in Figure 2.

Regarding **claim 54**, wherein said at least one attachment point that includes a plurality of attachment points that are interspersed among the plurality of through-holes, as shown in Figure 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 11, 12, 46, 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US 5,352,229), as applied to **claims 1, 2, 13, 16, 18, 21, 24-26 and 54** above, in view of Duncan (US 4,548,202). Goble et al. discloses a device comprising all the limitations recited in **claims 8, 11, 12, 46, 47 and 49**, with the exception of the device being produced from a biodegradable and biological material that is flexible and porous. However, the use of such a material in a medical implant device was known at the time the invention was made. Specifically, Duncan teaches the use of a mesh tissue fastener for "facilitate healing of a wound or incision" by providing "hemostatic compression to minimize bleeding, but allow some collateral blood circulation to the wound or incision edges of the tissue to promote healing" and allowing for the "capability to accommodated varying tissue thicknesses and... leave as little tissue cuff or margin as possible in effecting the joining of the tissue". Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Goble et al. by constructing it of a biodegradable and biological material that is flexible and porous because it is known in the art, as taught by Duncan, to use such a material in medical implant devices in order to provide a device that allows the tissue to heal while adjusting to fit into different configurations in the

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patient's body.

Claims 8, 46, 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US 5,352,229), as applied to **claims 1, 2, 13, 16, 18, 21, 24-26 and 54** above, in view of Tschakaloff (US 5,779,706). Goble et al. discloses a device comprising all the limitations recited in **claims 8, 46, 47 and 49**, with the exception of the device configured such that it is shapeable intra-operatively for use in a patient's body. However, the use of such a medical device was known at the time the invention was made. Specifically, Tschakaloff teaches the use of intra-operatively shaped devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Goble et al. by constructing it of a material capable of being shaped during surgery because it is known in the art, as taught by Tschakaloff, to use such a material in medical implant devices in order to adjust and mold the device fit properly into different configurations in the patient's body.

Claims 48 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US 5,352,229), as applied to **claims 1, 2, 13, 16, 18, 21, 24-26 and 54** above. Goble et al. teaches a device comprising all limitations recited in **claims 48 and 50**, but does not expressly disclose that the front and back sides of the backing **31** are concavely curved. At the time of the invention was made, it was well known to form implant devices in a curved configuration in order to more closely conform to the surface

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of tissue it is being implanted upon. Therefore, it would have been obvious to one having ordinary skill in the art to modify the backing front and back sides to be curved in a concave configuration as Applicant has done. Moreover, Applicant has not asserted that the specific configuration recited provides a particular advantage, solves a stated problem or serves a purpose different from that of a planar, or flat, backing, thus the use of curved surface of both the front and back sides of the backing lacks criticality in its design. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a planar backing because the device would still be fully capable of setting fragmented bones or repair bodily tissue. Therefore, it would have been obvious to modify the device of Goble et al. by altering the backing to have a curved surface because it is well known in the art to use a curved surface in an implant in order to more closely fit the contour of bodily tissue or bones.

Claims 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over **8, 46, 47** and **49** above, in view of Talpade (US 6,1 10, 100). Goble et al. teaches a device comprising all limitations recited in **claims 55-58**, with the exception of a therapeutic agent impregnated or coated on the device. However, the use of a therapeutic agent on a medical implant device was known at the time the invention was made. Specifically, Talpade teaches the use of a therapeutic agent being coated on or impregnated into a medical implant device for delivery of the therapeutic agent to aid the patient in recovery (column 8, lines 13-23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Goble et al. by

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coating or impregnating it with a therapeutic agent because it is well known in the art, as taught by Talpade, to deliver a therapeutic agent to a patient in this manner in order to aid the patient in healing and recovery.

(10) Response to Argument

In general, the Examiner is obligated to review and consider the claims in a reasonable interpretation, especially given the broad recitation of the claims. Therefore, the Examiner's interpretation that the attachment point in Goble extends from the front side of the backing in a non-orthogonal manner is reasonable. Furthermore, in claim 16, Applicant provides a Markush grouping of the attachment points which are an admission of equivalent configurations. In the Markush grouping, Applicant admits that an erect tine or erect nail-shaped tines, which are orthogonal arrangements, are equivalent to non-orthogonal arrangement such as canted hooks. Thus, given this admission of equivalence, there is no patentable distinction between the orthogonal versus the non-orthogonal arrangements. Therefore, the Goble reference would read upon both the orthogonal and the non-orthogonal arrangement.

Specifically, Applicant's arguments, with respect to the 102(b) rejection of **claims 1, 2, 13, 16, 21, 24-26 and 54**, filed July 22, 2005 have been fully considered but they are not persuasive. Regarding the amended claim limitation in **claim 1** stating "in a non-orthogonal manner" and Applicant's argument that the prior art of record—Goble (US 5,352,229)—does not teach or suggest the combination of a supportive backing and

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through-hole, with at least one attachment point extending from the backing in a non-orthogonal manner." The Examiner respectfully disagrees with this statement. The device has a supportive backing **31** with at least one through-hole **33, 34** formed therethrough and at least one attachment point **35** extending from the backing **31**, (column 5, lines 55-68), as shown in Figure 2. The attachment point 35 extends from the backing **31** in a non-orthogonal manner, since the sides of the extension to which attachment point **35** is connected; on the contrary, the angle is approximately 45°, which would make the "at least one attachment point **35** extending from front side backing **31** in a non-orthogonal manner." Therefore, the prior art of record still anticipates the claimed invention and the rejection for **claims 1, 2, 13, 16, 21, 24-26 and 54** under U.S.C. 102(b) is recapitulated hereinafter.

Applicant's arguments, with respect to the 103(a) rejection of **claims 8, 11, 12, 46, 47 and 49** have been fully considered but they are not persuasive. The Examiner would like to reiterate that it would have been obvious to one skill in the art at the time the invention was made to modify the device of Goble et al. by constructing it of a biodegradable and biological material.

Applicant's arguments, with respect to the 103(a) rejection of **claims 8, 46, 47 and 49** have been fully considered but they are not persuasive. The Examiner would like to reiterate that it would have been obvious to one skill in the art at the time the invention was made to modify the device of Goble et al. to be shapeable intra-operatively for use in a patient's body, as taught by Tschakaloff, for the purpose of proper fit.

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Applicant's arguments, with respect to the 103(a) rejection of **claims 48 and 50** have been fully considered but they are not persuasive. The Examiner would like to reiterate that it would have been obvious to one skill in the art at the time the invention was made to modify the device of Goble et al. by altering the backing to have a curved surface, in order to more closely fit the contour of bodily tissue or bones.

Applicant's arguments, with respect to the 103(a) rejection of **claims 55-58** have been fully considered but they are not persuasive. The Examiner would like to reiterate that it would have been obvious to one skill in the art at the time the invention was made to modify the device of Goble et al. by coating or impregnating it with a therapeutic agent to deliver a therapeutic agent to a patient as taught by Talpade.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Dinnatia Doster-Greene
Dinnatia Doster-Greene

Conferees:

Henry Bennett

[Signature]
Henry Bennett
Supervisory Patent Examiner
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